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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,471	08/29/2001	Gang Liu	6724.US.P1	7987

7590

06/04/2003

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 06/04/2003



Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,471

Applicant(s)

LIU ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The previous office action has been withdrawn.

Election/Restriction

I. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-75, drawn to compounds of formula (I) of non-heterocyclic pro-drugs, classified in class 514, subclass 534; class 560, subclass 41; class 562, subclass 405; class 562, subclass 553; class 558, subclass 23.

II. Claims 1-9, 11, 14-19, 22, 25, 30-35, 40-44, 49, 50-52, 55-58, 61-67, and 69-75, drawn to compounds of formula (I) of heterocyclic pro-drugs, classified in class 514, subclass 217; class 514, subclass 217.01; class 514, subclass 290; class 514, subclass 310; class 514, subclass 534; class 514, subclass 416; class 540, subclass 588; class 540, subclass 593, class 546, subclass 79, class 544, subclasses 106 and 122, class 546, subclasses 79, 143, and 184, class 548, subclasses 400 and 470, class 549, subclasses 29 and 200.

II. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case there are two different inventions I and II. The invention I is related to the side chain groups of the pro-drug consisted of alkyl, aryl, alkenyl, alkoxycarbonyl, alkylsulfonyl, arylalkylcarbonyl, whereas the invention II is related to the side chain

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alkylsulfonyl, arylalkylcarbonyl, whereas the invention II is related to the side chain groups of the heterocyclic pro-drug consisted of different kinds of heterocycles, such as pyrrolidine, piperidine, morpholine, homopiperidine, piperazine.

Furthermore, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

If the applicants elect the invention I, the invention I is further subjected to the election species due to a plurality of disclosed patentably distinct species comprising compounds of formula I.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the compounds of formula I in the invention I are generic. Applicants are advised to elect one species among the examples in the specification.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

On the other hand, if the applicants elect the invention II, the invention II is further subjected to the restriction.

III. Claims 1-9, 11, 14-19, 22, 25, 30-35, 40-44, 49, 50-52, 55-58, 61-67, and 69-75, drawn to the heterocyclic pro-drug containing various heterocycles further classified in the followings:

IIa. various groups in class 514 , subclasses 217, 217.01, 290, 310, 416, and 534;

IIb. a morpholino radical group in class 544, subclass 106;

IIc. a piperazino radical group in class 544, subclass 122;

IId. a piperidino group in class 546, subclass 184;

IIf. various groups in Class 546, subclasses 79 and 143;

IIg. various groups in class 548, subclass 470;

IIh. various groups of five-membered hetero ring in class 548, subclass 400;

IIi. a five-membered hetero ring with sulfur in class 549, subclass 29;

IIj. a five-membered hetero ring with oxygen in class 549, subclass 200 ;

IIk. various groups in class 540, subclasses 588 and 593.

IIj. various groups in class 540, subclasses 588 and 593.

Inventions IIa, IIb, IIc, IId, IIe, IIf, IIg, IIh, IIi , and IIj are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, for an example, there are two different inventions IIb and IIc. The invention IIb is related to the side chain group of the heterocyclic pro-drug consisted of the morpholino radical group, whereas the invention IIc is related to the side chain group of the heterocyclic pro-drug consisted of the piperazino radical group. Each invention has a different use and effect due to the unrelated substituent attached to the core of the compounds.

IV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

V. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

VI. A telephone call was made to Rogers Christopher on 5/31/2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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VII. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

VIII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-2742 for regular communications and 703-305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Taylor V Oh
5/31/03